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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/369,735

08/06/99

MATSUI

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HM12/0531

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EXAMINER

MONSHIPOURI, M

ART UNIT

PAPER NUMBER

1652

8

DATE MAILED:

05/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/369,735

Applicant(s)

Matsui et al.

Examiner

Maryam Monshipouri

Group Art Unit

1652



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-11 is/are pending in the application

Of the above, claim(s) 3-11 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 2 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1652

Applicant's response to restriction requirement filed 4/18/2000 (paper #8) is acknowledged. Elected claims 1-2 are under examination on the merits. Claims 3-11 are withdrawn from further examination as drawn to non-elected invention.

Specification

1. The specification is objected to for having two sequence listings. The first sequence listing pages 28-35 is identical to the sequence listing corresponding to pages 1-7, inserted after the claims. Applicant is advised to cancel one of said sequence listings in order to avoid confusion. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:2, does not reasonably provide enablement for its variants wherein a plurality of amino acid residues are mutated. The criteria for undue experimentation is summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims. The specification merely defines a single amino acid sequence having

Art Unit: 1652

glycosidase activity. In page 3 of the specification, applicant refers to some preferred embodiments of SEQ ID NO:2 variants wherein 1-30 or more preferable 1-18 amino acid residues are mutated as long as enzyme activity is retained. However, claim 1 as recited does not specify these variant structural limitations which can have a "plurality" of amino acids within SEQ ID NO:2, mutated. Said claim, in fact, is directed to any amino acid composition from any source having glycosidase activity. No examples of such variant sequences are provided either. Current state of prior art indicates that any amino acid composition from any source having glycosidase activity needs to have little/if any structural homology to SEQ ID NO:2 of this invention. Therefore, based on lack of structural limitations provided, and due to lack of any relevant examples of variants of SEQ ID NO:2 and due to unpredictability of prior art with regards to structural requirements of glycosidase enzymes that can be considered to be SEQ ID NO:2 variants of this invention, the metes and bounds of said claims are unclear and one of skill in the art has to go through the burden of undue experimentation in order to recognize such SEQ ID NO:2 variants among the numerous number of enzymes having glycosidase activity. Hence, said claims go beyond the scope of the disclosure.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Art Unit: 1652

5. Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-2 are directed to a thermophilic beta-glycosidase present in *Pyrococcus horikoshii* which is a product of nature and therefore is unpatentable. Applicant is advised to recite the term "isolated" or "purified" into claim 1, prior to "thermophilic enzyme", in order to overcome this rejection.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bylina et al. (WO 97/25417, 17 July 1997). Bylina et al. disclose a thermostable glycosidase enzyme, amino acid sequence of which has 85.4% homology (see the attached alignment data) to SEQ ID NO:2 of this invention, anticipating claim 1. They also disclose that glycosidase of their invention were obtained from (see abstract) from pyococcus organisms which grow optimally at 100°C (see page 9) implying that the glycosidase obtained from said organism is likely to operate well at 100°C, anticipating claim 2.

8. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Ladrat et al. (J. Mar. Biotechnol., 4, 192-199, 1996). Ladrat et al. teach a thermostable beta glycosidase from

Art Unit: 1652

Pyococcus whose physicochemical properties such as pH and optimal temperature are identical to the enzyme claimed instantly. Although, the exact amino acid sequence of glycosidase of Ladrat et al. is not disclosed, because of its identical optimal pH and temperature to the enzyme claimed instantly it is believed to have some homology to SEQ ID NO:2 of this invention, and can be considered to be a variant of SEQ ID NO:2, anticipating claim 1-2. The difference between the molecular weight of their enzyme (64 KD) and that of this invention (47 KD) may be considered to be due to "additional" type mutation of SEQ ID NO:2.

8. No claims are allowed.

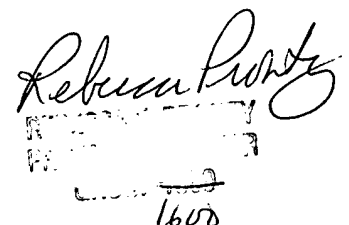
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083. The examiner of record can normally be reached daily from 8:00 a.m. to 5:00 p.m. except for Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Maryam Monshipouri, Ph.D.

Patent Examiner



Rebecca Priddy

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